

**Prepared Testimony of
Dr. Robert Eckel
Immediate Past President, American Heart Association
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United States House of Representatives
“National Institutes of Health Reform Act of 2006”
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Chairman Barton, Congressman Dingell and Members of the Committee, on behalf of the American Heart Association (AHA) and our more than 22 million volunteers and supporters, I want to thank you for this opportunity to present our views on the “National Institutes of Health Reform Act of 2006” and for your leadership in taking on this issue of such great importance to our nation and fellow citizens.

I am saddened to report today that cardiovascular disease (CVD) remains the number one and most costly killer of Americans, and is fast becoming a worldwide epidemic – one of the so-called diseases of development. However, there is hope. Medical research can help reverse these lethal trends, and holds the key to an eventual cure for heart disease, stroke and all other forms of cardiovascular disease.

The American Heart Association has set the ambitious but feasible target of reducing cardiovascular disease and risk by 25 percent by the year 2010. And as major stakeholders in this debate, we have carefully reviewed the legislation before the Committee, and concluded that its proposed changes can help put us on the right path to meeting this goal.

Research Makes a Difference

Mr. Chairman, over the past 50 years, we have made enormous progress in the battle against cardiovascular disease. As many of us know from personal experience and loss, it was once all too common for a person who suffered a heart attack or stroke to die, or be severely debilitated or disabled following one.

In those early years of the CVD fight, the tools available to medical practitioners and researchers for diagnosis and treatment were limited, funding was scarce, and the problem was compounded by the fact that the vast majority of Americans knew little about what they could do in their day-to-day lives to help prevent this horrible and potentially lethal affliction.

However, through a strong partnership between the federal government and the medical research community and deliberate and focused action, we have made great strides since those first days. From the groundbreaking Framingham Heart Study and other studies that advanced our understanding of CVD risk factors, to new drugs, such as clot-busters and statins, we have witnessed first-hand what can be accomplished through medical research.

The improved diagnosis and treatment of heart disease and stroke has also been nothing less than remarkable – as has the improved survival rate. Indeed, according to the NIH, we have saved 1.6 million lives since the 1960s that otherwise would have been lost to heart disease. Much of this progress can be attributed to our investment in NIH-sponsored heart and stroke research.

New Challenges Threaten Our Ability to Achieve Goals

In spite of this progress in the war against cardiovascular disease, we are far from declaring victory. An estimated 71 million American adults now suffer from heart disease, stroke, and other forms of CVD. The morbidity and mortality rates are still staggering. Nearly 2,500 Americans die of CVD each day – an average of one death every 35 seconds. That is the equivalent of losing one entire small town in America every 24 hours. The alarming truth is that we may be losing ground. Although we have increased our educational efforts, studies suggest that increased rates of diabetes, obesity and other risk factors may reverse four decades of declining mortality

In addition, demographics will soon worsen the situation. As the baby boom generation ages, the prevalence of cardiovascular disease will increase dramatically, because although this disease can strike at any stage of life – the likelihood increases with age. Deaths from heart disease alone are projected to increase 2.5 times faster than the population. Mortality from the most common type of stroke is projected to increase by nearly 100 percent between 2000 and 2032. Beyond the toll in human suffering and death, cardiovascular disease also comes with a steep price tag. It will cost Americans an estimated \$403 billion in medical expenses and lost productivity in 2006 – more than any other disease and more than the projected budget deficit for this year. We will soon face a cardiovascular crisis of staggering proportions, with major implications for health care costs and quality of care for our fellow citizens.

Reforms in this Bill Address These Challenges

We strongly believe that the reforms proposed in this legislation are both prudent and necessary to help address these challenges. In 2002, the AHA testified before the Institute of Medicine (IOM) on NIH's "optimal organization structure." We recommended four key principles – transparency, flexibility, collaboration, and translation – to guide this ideal architecture. Many were reflected in IOM's recommendations issued in 2003 and are in turn, embodied in the legislation before the Committee today.

For example, the creation of a new Division for Program Coordination, Planning, and Strategic Initiatives will give the Director the *flexibility* needed to respond to emerging disease threats in an agile, comprehensive and coordinated manner that does not exist today. The creation of a common research fund to support more trans-NIH research recognizes the need for *collaboration* on problems like obesity, which is a significant risk factor for heart disease, stroke, diabetes, cancer, and other diseases, and also supports clinical research, which helps enable the *translation* of basic research into patient care. In addition, the new agency-wide performance system and consolidated reporting would help promote greater *transparency*, produce more accurate and credible data on disease funding and outcomes, and enable patient advocacy groups to use this data to make a strong and credible case for federal funding for medical research.

The bill authorizes 5 percent increases for NIH for each of the next three fiscal years (FY 2007-2009.) We would ideally have hoped for a higher level. Since the end of the so-called “doubling period,” funding for NIH has declined in real terms (adjusted for medical research inflation) in every year; it would take an increase of more than 10 percent in FY 2007 just to restore NIH to its post-doubling level. However, we recognize the current budget realities: the level set for FY 2007 reflects budget recommendations made by the American Heart Association and the broader medical research community. If we can match these reforms with the stable funding commitment recommended in the bill, the American Heart Association believes that we can be much more successful in the research needed to confront and overcome the terrible cardiovascular crisis that threatens to overwhelm the health and economic well-being of our nation – and the world.

I would now like to turn to the Association’s specific observations and recommendations about key proposals in the legislation.

The Common Fund

In addition to promoting “shared funds” controlled by the Institutes’ and Centers’ directors, the legislation would establish a “common fund” to focus entirely on trans-NIH research projects – those that may cut across more than one disease, or where one disease or risk factor may influence another. This provision implements IOM’s recommendation to “enhance and increase trans-NIH strategic planning and funding,” and we agree that interdisciplinary interaction is critical to promoting new initiatives and aligning medical research.

Two recent examples of trans-NIH research funding illustrate the tangible benefits of collaborating on cardiovascular disease: (1) the NIH strategic plan for obesity research; and (2) the NIH blueprint for neuroscience research.

Obesity is a major risk factor for heart disease and stroke, as well as for many other diseases, including diabetes, certain cancers, liver disease, osteoarthritis, sleep apnea, and depression. And obesity does more than affect life lines; it also affects government’s bottom line – costs. According to a recent study by economists Kenneth Thorpe and David Howard, obesity and other chronic conditions were major factors driving virtually all Medicare spending growth for the past 15 years. The rate of obesity among Medicare patients doubled from 1987 to 2002, and spending on those individuals rose more than twofold.

The increase in obesity over the past 30 years has been fueled by a complex interplay of many factors and calls for a broad spectrum of research, including molecular, genetic, behavioral, environmental, epidemiological, and clinical studies. The NIH strategic plan for obesity research provides a guide for coordinating obesity-related research activities across the organization based on the identification of areas of greatest scientific opportunity and challenge. It is a wise choice as these well-invested taxpayer dollars will not only focus on the genetic and environmental basis of obesity and diabetes and establish an evidence-based approach for prevention, but also go towards reducing disability and death from cardiovascular disease. Moreover, through joint efforts with our private sector colleagues, more effective therapies of prevention and management will certainly ensue.

The NIH blueprint for neuroscience research is supported by 15 Institutes and Centers. Blueprint initiatives have focused on neuroscience tools, training in the neurobiology of disease for basic science, genome analysis, neuroimaging, genetic mouse models, core research facilities, and clinical assessment tools. By pooling resources and expertise, this collaborative effort helps advance neurosciences and the emergence of new technologies that will lead to breakthroughs in stroke and other brain disorders.

These are just two examples of the many collaborative efforts within the NIH that increase the effectiveness of the nation's investment in health-related research

Authorizations for the Common Fund

We are pleased that the draft legislation sets a ceiling on trans-NIH research at five percent – the same level as recommended in the IOM report. If the NIH receives increases assumed in the draft legislation of five percent-a-year through FY 2009, the Common Fund could reach the targeted five percent level as early as FY 2008.

Agency-wide Reporting System

The AHA supports the creation of an agency-wide electronic reporting system to catalogue NIH's research activities in a standardized format. The current decentralized data collection mechanisms make it difficult to determine how much has been spent on cardiovascular research and for what purposes. This year, for example, cardiovascular-related research was conducted by 18 Institutes and Centers, with their own distinct methods of reporting.

Other provisions in the bill would require the Director to submit biennially a report to Congress that lays out the strategic plans and research activities of the entire agency in a comprehensive fashion. As previously noted, these new reporting requirements should help increase the transparency of NIH research activities and give us the information we need to make a compelling case for adequate research funding.

Nevertheless, we are concerned that Section 403(a)(5) of the bill neglects to require a separate category for heart disease and stroke – the number one and number three killers of Americans, respectively, in the biennial report of the Director. We urge the Director to include a separate subsection for cardiovascular disease, or to include information for heart disease and stroke under the appropriate category in the same standardized format as all other diseases, disorders, and other adverse health conditions.

Strategic Planning Process

The Association supports the proposed strategic planning process that transcends – but does not supplant – the planning, priority setting, and research activities of individual Institutes and Centers. Many of these changes are being implemented now through the Office of Portfolio Analysis and Strategic Initiatives (OPASI). The proposed new Division of Program Coordination, Planning, and Strategic Initiatives would carry on these activities.

One objective of this new coordinating function is to identify and plan for emerging scientific opportunities and rising health challenges that involve collaboration between two or more Institutes or Centers. Given its “Number One” killer status, we strongly recommend that cardiovascular disease be included as one of the challenges to be addressed in the strategic planning process. As part of this planning process, we urge the Division to develop long-term projections of the incidence and prevalence of chronic diseases in coordination with other appropriate Federal agencies. These long-term projections would help guide research efforts aimed at reducing the economic and health burden of an aging population.

Scientific Management Review Board

The bill would create an advisory council or “Scientific Management Review Board” to periodically review the NIH’s structural organization. The Association supports the requirement that the Board include the Directors of at least nine Institutes and Centers. We also support the requirement that the Board consult with organizations representing patients and that at least one Board meeting should address the needs and opportunities of patients and their families. We believe that the American Heart Association should be among the groups with which the Board consults on the NIH’s organization, as we are able to represent both patient and family views.

Conclusion

The AHA is heartened that Chairman Barton and the Committee recognize and appreciate the important role of patient stakeholders in NIH’s mission. We have made considerable progress over the years, but face daunting challenges in the years ahead. We support this legislation because we believe that the organizational and other changes recommended in this bill will help direct resources more effectively to current health concerns, and help bring about the achievements in research necessary to confront the cardiovascular crisis that threatens the health and economic well-being of our nation and the world.